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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/683,885

10/10/2003

Daren L. Stewart

667P

7851

7590
Thomas M. Freiburger
P.O. Box 1026
Tiburon, CA 94920

05/12/2010

EXAMINER

LACYK, JOHN P

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

05/12/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/683,885	Applicant(s) STEWART ET AL.	
	Examiner John P. Lacyk	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-50 and 53-137 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-50 and 53-137 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/18/09; 1/27/10</u> . | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 135-137 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 135 is considered to be incomplete in that the only method step is to applying a vacuum to draw tissue towards said treatment assembly, however there are no steps directed to deploying the treatment assembly within the body.

In claim 136, lines 5-6, the treatment assembly lacks positive antecedent basis in that the treatment assembly is not a positively claimed element, it has only been inferentially defined in the preamble. The treatment assembly should be positively defined since as can be seen in claim 137 the treatment assembly is being further defined.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 41 claims a surface relief means, however there is no antecedent basis in the specification for such a means or exactly what is included in such a means.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 136-137 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams (5,611,767).

Williams discloses a device for treating tissue adjacent to a body cavity that has an inner balloon assembly (28A) including an inflation conduit to allow passage of fluid and an inner balloon and a sheath assembly or outer balloon (28B) having a conduit and a fluid-permeable sheath wall that encloses the inner balloon assembly. While the Williams device does not specifically teach using a vacuum, the vacuum source is not a positively claimed element and the Williams device does provide all the claimed structure and is capable of providing a vacuum as claimed if connected to a vacuum source, therefore it is considered to be "configured to provide" suction or a vacuum, or "configured to be in fluid communication" with a vacuum source. The outer balloon (28B) is considered to be a "raised exterior portion" to space tissue from an exterior portion of the cavity filling member or inner balloon assembly (28A).

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Claims 41-50 and 53-137 are rejected under 35 U.S.C. 102(e) as being anticipated by Lubock (6,955,641 and 6,923,754).

Both Lubock references disclose a device having an inflatable balloon, a flexible shaft secured to the balloon that extends outside of the body cavity having a lumen to inflate the balloon. Lubock also teaches a "surface relief means" on the exterior of the balloon for providing channels when the balloon is inflated, the surface relief means being a second balloon enclosing the first balloon, the second balloon includes holes that are exposed to the body cavity and has ribs to form channels between the first and second balloons. While the Lubock references do not specifically teach allowing liquids to drain via the channels, the channels are connected to a vacuum source to provide for a vacuum to conform the body cavity to the outer balloon. In providing a vacuum to conform the body cavity the device would inherently suction out any liquids that happen to be in the body cavity.

Applicant's arguments filed 11/17/09 have been fully considered but they are not persuasive. Applicant submits a declaration under 37 CFR 1.131 in response to the rejection of claims under 102(e) to show an effective filing date prior to the Lubock references, however the declaration, as discussed in M.P.E.P. 715.07, is considered to insufficient, as only one example,

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The affidavit or declaration and exhibits must clearly explain which facts or data applicant is relying on to show completion of his or her invention prior to the particular date. Vague and general statements in broad terms about what the exhibits describe along with a general assertion that the exhibits describe a reduction to practice "amounts essentially to mere pleading, unsupported by proof or a showing of facts" and, thus, does not satisfy the requirements of 37 CFR 1.131(b). *In re Borkowski*, 505 F.2d 713, 184 USPQ 29 (CCPA 1974). Applicant must give a clear explanation of the exhibits pointing out exactly what facts are established and relied on by applicant. 505 F.2d at 718-19, 184 USPQ at 33. See also *In re Harry*, 333 F.2d 920, 142 USPQ 164 (CCPA 1964) (Affidavit "asserts that facts exist but does not tell what they are or when they occurred.").

Applicant's declaration is submitted to show an effective date prior to the Lubock references, as discussed above, the declaration is considered to be insufficient, the declaration "must clearly explain which facts or data applicant is relying on to show "completion" of his or her invention prior to the particular date. As only one example, entry #17 discusses the use of ribs inside the balloon with a date of 4/30/03 which is clearly after the filing date of the Lubock references clearly not showing "completion" of the claimed invention prior to the filing date of the Lubock references. The declaration appears to show that the device was still being designed and that the device was not completed or reduced to practice prior to the filing date of the Lubock references. Entry #3 dated 10/07/02 is the first entry listed before the filing date of the Lubock references and discusses that the idea of a drain port/membrane on the applicator was considered, but also clearly shows that the device was not in any way completed or in reduced to practice prior to the filing date of the Lubock references, just because someone thinks of an idea or concept does not mean they invented or completed the invention. It appears

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that the applicant's were still working on the design and completion of their invention well after the filing date of the Lubock references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (571)272-4728. The examiner can normally be reached on 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.P. Lacyk

/John P Lacyk/
Primary Examiner, Art Unit 3735